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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,371	10/03/2003	Benjamin V. Treadwell	030229	4023

26285 7590 08/27/2007

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EXAMINER	
KIM, JENNIFER M	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
08/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/678,371	TREADWELL, BENJAMIN V.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) *6 and 30-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-29,65 and 66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed June 19, 2007 have been received and entered into the application.

Action Summary

The rejection of claims 1-5, 7-11,13-22 and 27-29 under 35 U.S.C. 103(a) as being unpatentable over Babish (U.S 2003/0054978 A1) in view of Rath (U.S.Patent No. 6,693,129 B2) is being maintained for the reasons stated in the previous Office Action. However, the rejection is modified in this Office Action to address newly added claims 65 and 66, and the amended claim limitations.

The rejection of claims 1, 12 and 23-29 under 35 U.S.C. 103(a) as being unpatentable over Babish (U.S 2003/0054978 A1) in view of Gonzales Bravo et al. (U.S.Patent No. 6,486,205 B2) is being maintained for the reasons stated in the previous Office Action. However, the rejection is modified in this Office Action to address the amended claim limitations.

Response to Arguments

Applicant's arguments filed June 19, 2007 have been fully considered but they are not persuasive. Applicant argues that the cited references are nonanalogous art, and notwithstanding, none of the cited references, alone or in combination, teach or suggest to one skilled in the art a composition comprising a long-chain normal primary aliphatic alcohol in combination with a B12 vitamin, a D vitamin, coenzyme Q, an omega-3 fatty acid or combinations thereof for treatment of autoimmune diseases or immuno-inflammatory diseases. This is not found persuasive because with respect to the combination of Babish and Rath references, each of the references teaches that the each of the active agents are useful in a composition for treatment of hyperlipidemia. These two references are both in the same field involving cardiovascular disease wherein the risk factors such as hyperlipidemia are effectively treated with the active agents employed as effective components. Therefore, these references are analogous art to the instant invention wherein both references teach the effective utilization of the active components in a therapeutic composition for the treatment of a disease.

With respect to the combination of Babish and Gonzales Bravo references, again, each of the references teaches that each of the active agents is useful in a therapeutic composition because the active agents are useful for treating the same disorder of hyperlipidemia. These two references are both in the same field involving cardiovascular disease wherein the risk factors such as hyperlipidemia are effectively treated with the active agents as effective components for the treatment of such diseases. Therefore, both references teach the formulation of each of the active agents in a composition effective for hyperlipidemia therapy. Applicants' limitation of the

intended use to attenuating at least one factor involved in the inflammation-associated destruction of tissue associated with autoimmune disease or immuno-inflammatory diseases is noted. However, the motivation to combine need not be Applicant's motivation to invent. *In re Dillon* 16 USPQ 2d 1897, (Fed. Cir. 1990). In this case, the motivation for combining the components flows from their individually known common utility of the treatment of hyperlipidemia (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). Applicant argues that the cited references are neither in the field of Applicant's endeavor (i.e. treatment of autoimmune diseases or immuno-inflammatory diseases), and one of ordinary skill in the art would not consider compositions for treating CAD (cardiovascular arterial disease) and hyperlipidemia to be reasonably pertinent to the treatment of autoimmune disease because they are nonanalogous art. This is not persuasive because Applicant is reminded that the instant claims are drawn to "composition" claims not "method" claims. It has been held that the determination that a reference is nonanalogous art is two fold. First, we decide if the reference is within the field of the inventor's endeavor. If it is not, we proceed to determine whether the reference is reasonably pertinent to the particular problem with which the inventor was involved. In re Wood, 202 USPQ 171, 174. In this case, these references are analogous art because they both teach that the each of the active agents is useful in a pharmaceutical composition for the treatment of a hyperlipidemic condition. The instant claims are drawn to "composition" claims which are Applicant's endeavor. Likewise, the cited references teach that the each of active agents can be combined in a single composition as a therapeutic composition for the treatment of hyperlipidemia. The fact

that applicant has recognized another use which differs from the suggestion of the cited prior art cannot be the basis for patentability in the instantly claimed "composition" claims because such fails to impart a physical difference in the obvious combination from the cited prior art. Accordingly, the references are within the field of the inventor's endeavor of the instantly claimed therapeutic "composition". Applicant argues that for Babish to serve as the primary reference under 35 U.S.C. 103(a) rejection, one of ordinary skill must justify eliminating arginine from the composition disclosed because Babish provides no teaching nor suggestion that the arginine in the disclosed compositions is dispensable or interchangeable with additional components. This is not found persuasive because the instant claims are drawn to a therapeutic composition "**comprising**". The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements. (See MPEP 2111.03). In this case, the way the instant claims are drawn to a therapeutic composition "comprising" does not exclude or eliminate the arginine employed by Babish et al. Therefore, Babish et al's composition comprising arginine still lies within the scope of the claim. Alternatively, even if the claims were drawn to exclude arginine, it still doesn't change the teaching of Babish that all of the disclosed components are useful in formulating a therapeutic composition for treating hyperlipidemia. Babish clearly teaches and suggests that these components are useful in a composition for therapeutic use in hyperlipidemic conditions. Applicant argues that Rath fails to provide any teaching or suggestion regarding the importance of coenzyme Q10 and cholescalciferol apart from the 35 other disclosed ingredients and

that the Office can not identify a reason why a person of ordinary skill in the art would take the composition of Rath, consisting of 37 active ingredients, and randomly choose two of the 37 ingredients (to the exclusion of the other 35) to add to the secondary components of the composition of Babish. This is not persuasive because these active agents have already been identified as useful components for a therapeutic composition for the treatment of hyperlipidemia by Rath. Rath teaches that a composition comprising cholescalciferol (vitamin D3) and coenzyme Q10 is useful for lowering the risk factors for cardiovascular disease including hyperlipidemia. Therefore, it would have been obvious to one of ordinary skill in the art to combine the composition of Rath comprising cholescalciferol (vitamin D3) and coenzyme Q10 and Babish's composition together in a single formulation in order to achieve at least an additive therapeutic effect in treating hyperlipidemia. Applicant argues that claim 1 of Rath recites a composition "consisting of" of all 37 ingredients and that the transition phrase "consisting of" excludes any ingredient not specified in the claim. The examiner is in agreement with Applicant's definition of the transition phrase "consisting of " excluding any ingredients not specified in the claim. However, it does not change the fact that each of the active agents, including Coenzyme Q10 and cholescalciferol, exemplified in Rath's Example 1 are useful ingredients in the preparation of a representative pharmaceutical composition for the treatment of hyperlipidemia taught by Roth et al. Rath's claim 1 limited to those active agent's recited in claim 1, does not teach away from what is taught in the specification including the disclosed examples and preferred embodiments of Rath. Applicant argues that one of ordinary skill in the art would not randomly select two

nondescript ingredients, ignore 35 other equally important active ingredients, add the two nondescript ingredients to secondary ingredients form a different pharmacological composition and expect that the resulting composition would function to treat a class of diseases completely different than the class of diseases the original composition were intended to treat. This is not found persuasive because Rath's exemplified and preferred embodiment shows the preparation of a representative pharmaceutical composition containing cholescalciferol and coenzyme Q10 useful for the treatment of hyperlipidemia. Therefore, it would have been obvious to combine the composition containing cholescalciferol and coenzyme Q10 with Babish's composition with a reasonable expectation of successfully treating hyperlipidemia, because both compositions are taught to be effective for such treatment in each of the references. Applicant argues that one of ordinary skill in the art would not add the fatty acid mixture of Gonzales-Bravo to secondary ingredients from a different pharmacological composition and expect that the resulting composition would function to treat a class of diseases completely different than the class of diseases the original compositions were intended to treat. This is not found persuasive because Gonzales Bravo reports that mixtures of fatty acids, especially eicosapentaenoic and docosahexaenoic acids, are useful in a pharmaceutical formulation as active agents for treating and lowering cholesterol and lipid activity and numerous patents have appeared with this teaching in the last decade. These teachings are clear as to the usefulness of mixtures of fatty acids, especially eicosapentaenoic and docosahexaenoic acids as active agents in a pharmaceutical formulation for treating a hyperlipidemic condition. Therefore, it would

have been obvious to one of ordinary skill in the art to combine mixtures of fatty acids, especially eicosapentaenoic and docosahexaenoic acids with Babish's composition in order to achieve at least an additive effect in treating hyperlipidemia. There is a reasonable expectation of successfully formulating a pharmaceutical formulation for treating hyperlipidemia by adding mixtures of the fatty acids to Babish's composition because these mixtures of fatty acids are well known for decades for the treatment of a hyperlipidemic condition in view of Gonzales Bravo. Applicant argues that the Office cannot establish the obviousness of the compositions for treating autoimmune disease claimed in the present application by describing a miscellaneous amalgam of various ingredients randomly selected form references that teach particular compositions for treating hyperlipidemia which is a completely unrelated class of disease and that claims 1, 65 and 66 of the present application are not rendered obvious by the cited references because they are nonanalogous art and they do not teach or suggest to one of ordinary skill in the art the claimed compositions for the treatment of autoimmune disease. This is not found persuasive because the motivation to combine need not be Applicant's motivation to invent. *In re Dillon* 16 USPQ 2d 1897, (Fed. Cir. 1990). In this case, each of the references teaches compositions that are useful in treating hyperlipidemia. Therefore, it would have been obvious to combine each of the compositions taught by the references in order to achieve at least an additive effect in treating hyperlipidemia. The motivation for combining the components flows from their individually known common utility of treating hyperlipidemia (see In re Kerkhoven, 205 USPQ

1069(CCPPA 1980)). Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7-11, 13- 22, 27-29, 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babish (U.S 2003/0054978 A1) in view of Rath (U.S.Patent No. 6,693,129 B2).

Babish teaches a composition comprising mixtures of aliphatic alcohol, such as **1-tricontanol,** and vitamin B12, such as **methylcobalamin,** useful for the treatment of cardiovascular arterial disease risk factors such as hypercholesterolemia, hypertriglyceridemia and hyperlipidemia. (abstract, [0017], [0024]-[0030], Table 1, [0039], claims 5, 15). Babish teaches that the amount of aliphatic alcohol to be employed is from about 0.001 to 1000mg and can also be within 0.5 to 100mg. (claims 11, 12). This amount is within Applicants amount set forth in claims 13-15. Babish teaches that the amount of vitamin B12, such as methylcobalamin, to be employed is about 0.0001 to 1000mg. (claim 12). This amount is within Applicants amount set forth in claims 16-20). Babish teaches that the composition can be formulated in the form of solid capsules, caplets, tablets, softgels, liquids, bars and functional food and other convenient forms such as a solution, suspension or a spray solution. ([0054], claim 14). (see Applicant's claim 29). Babish teaches that the composition can be further combined with vitamins, minerals, proteins, fats, carbohydrates, natural plant products, and antioxidants. (claim 13). (see Applicant's claim 27). Babish teaches that pharmaceutically acceptable carriers such as diluents, binders, additives, donating agents, buffers and disintegrants can be employed in the composition. ([0053]. (see Applicant's claim 28).

Babish does not teach cholecalciferol (Vitamin D3) and Coenzyme Q10 and their amounts effective for the treatment of cardiovascular disease, including hyperlipidemia, in a single composition.

Rath teaches a composition comprising **cholecalciferol (Vitamin D3)** and **Coenzyme Q10** useful for lowering the risk factors for cardiovascular disease, including arteriosclerosis, cerebrovascular disease and hyperlipidemia, by lowering cholesterol, LDL-cholesterol, triglycerides and other metabolic risk factors. (abstract, column 3, paragraphs 3, 4,6 7, Examples). Rath teaches Coenzyme A10 to be employed at 7mg dosage. (Example 1). This dosage is within Applicant's amounts set forth in claims 21 and 22. Rath teaches cholecalciferol to be employed at 3.3 mcg. (Example 1). This amount is within Applicant's amount set forth in claims 19 and 20.

It would have been obvious to one of ordinary skill in the art to add cholecalciferol and coenzyme Q10 to Babish's composition for the treatment of hyperlipidemia because Rath teaches that composition comprising cholecalciferol and coenzyme Q10 and their effective amounts for the treatment of hyperlipidemia. One would have been motivated to combine cholecalciferol and coenzyme Q10 in Babish's composition in order to achieve an expected additive effect in the treatment of hyperlipidemia. There is a reasonable expectation of successfully treating hyperlipidemia with the composition of Babish combined with cholecalciferol and coenzyme Q10 because each of the active agents possesses the same effect. The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). Accordingly, it would be expected that the combination of components would treat hyperlipidemia conditions as well. With regard to the limitation of the intended use of attenuating at least one factor involved in the inflammation-associated destruction for tissue associated with autoimmune disease or immuno-

inflammatory disease, it is noted that the motivation to combine mentioned above need not be Applicant's motivation to invent. *In re Dillon* 16 USPQ 2d 1897, (Fed. Cir. 1990).

Claims 1, 12 and 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babish (U.S 2003/0054978 A1) in view of Gonzales Bravo et al. (U.S.Patent No. 6,486,205 B2).

Babish teaches a composition comprising mixtures of aliphatic alcohol, such as **1-tricontanol,** and vitamin B12, such as **methylcobalamin,** useful for the treatment of cardiovascular arterial disease risk factors such as hypercholesterolemia, hypertriglyceridemia and hyperlipidemia. (abstract, [0017], [0024]-[0030], Table 1, [0039], claims 5, 15). Babish teaches that the composition can be formulated in form of solid capsules, caplets, tablets, soft gels, liquids, bars and functional food and other convenient forms such as a solution, suspension or a spray solution. ([0054], claim 14). (see Applicant's claim 29). Babish teaches that the composition can be further combined with vitamins, minerals, proteins, fats, carbohydrates, natural plant products, and antioxidants. (claim 13). (see Applicant's claim 27). Babish teaches that pharmaceutically acceptable carriers such as diluents, binders, additives, donating agents, buffers and disintegrants can be employed in the composition. ([0053]. (see Applicant's claim 28).

Babish does not teach eicosapentaenoic acid, docosahexaenoic acid and their amounts effective for the treatment of cardiovascular disease, including hyperlipidemia in a single composition.

Gonzales Bravo et al. report that in the last decade, numerous patents have appeared which report that the omega-3-poly-unsaturated fatty acids have an effect on serum cholesterol. (column 1, lines 37-67). Gonzales Bravo et al. teach mixtures of fatty acids, especially eicosapentaenoic and docosahexaenoic acids, in daily doses that varies from 500mg/kg of body weight to 0.5-30g are useful in a pharmaceutical formulation as active agents for treating and lowering cholesterol in blood and for having serum lipid-improving activity. (column 1, line 63- column 2, line 3).

It would have been obvious to one of ordinary skill in the art to add fatty acids such as eicosapentaenoic acid and docosahexaenoic acid to Babish's composition comprising mixtures of aliphatic alcohol, such as **1-tricontanol,** and vitamin B12, such as **methylcobalamin,** because the fatty acids such as eicosapentaenoic acid and docosahexaenoic acids are also useful for treating and lowering cholesterol in blood and improving serum lipid activity. One would have been motivated to make such a modification in order to achieve at least an additive effect in treating and lowering cholesterol in the hyperlipidemia patient disclosed by Babish. It would be expected that the combination of all components would treat hyperlipidemic conditions as well. The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). With regard to the limitation of the intended use of attenuating at least one factor involved in the

inflammation-associated destruction for tissue associated with autoimmune disease or immuno-inflammatory disease, it is noted that the motivation to combine mentioned above need not be Applicant's motivation to invent. *In re Dillon* 16 USPQ 2d 1897, (Fed. Cir. 1990).

Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

None of the claims are allowed.

In the previous Office Action, the first rejection incorrectly includes claim 6. The cover sheet form-326 for that action correctly indicates that claim 6 is withdrawn from consideration. The summary of the previous Office Action on page 2 herein also indicates that the first rejection in the previous Office action excludes claim 6.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Kim
Patent Examiner
Art Unit 1617

Jmk
August 20, 2007